

PART III – LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

ATTACHMENT J-7 – QUALITY ASSURANCE PROJECT GRADED APPROACH

Contractor shall submit a QA Program compliant with EM Corporate QAP (EM-QA-001 Rev 1) using the graded approach as prescribed in the following criteria from DOE O 414.1D.

Graded Approach.

The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with:

- (1) the relative importance to safety, safeguards, and security;
- (2) the magnitude of any hazard involved;
- (3) the life-cycle stage of a facility or item;
- (4) the programmatic mission of a facility;
- (5) the particular characteristics of a facility or item;
- (6) the relative importance to radiological and nonradiological hazards; and,
- (7) any other relevant factors. (10 C.F.R. § 830.3)

QUALITY ASSURANCE CRITERIA

1. Criterion 1— Management/Program

- a. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
- b. Establish management processes, including planning, scheduling, and providing resources for the work.

2. Criterion 2— Management/Personnel Training and Qualification

- a. Train and qualify personnel to be capable of performing their assigned work.
- b. Provide continuing training to personnel to maintain their job proficiency.

3. Criterion 3— Management/Quality Improvement

- a. Establish and implement processes to detect and prevent quality problems.
- b. Identify, control, and correct items, services, and processes that do not meet established requirements.
- c. Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.
- d. Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.

4. Criterion 4— Management/Documents and Records

- a. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
- b. Specify, prepare, review, approve, and maintain records.

5. Criterion 5— Performance/Work Processes

- a. Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means.
- b. Identify and control items to ensure proper use.
- c. Maintain items to prevent damage, loss, or deterioration.
- d. Calibrate and maintain equipment used for process monitoring or data collection.

6. Criterion 6— Performance/Design

- a. Design items and processes using sound engineering/scientific principles and appropriate standards.
- b. Incorporate applicable requirements and design bases in design work and design changes.
- c. Identify and control design interfaces.
- d. Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.
- e. Verify or validate work before approval and implementation of the design.

7. Criterion 7— Performance/Procurement

- a. Procure items and services that meet established requirements and perform as specified.
- b. Evaluate and select prospective suppliers on the basis of specified criteria.

- c. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

8. Criterion 8— Performance/Inspection and Acceptance Testing

- a. Inspect and test specified items, services, and processes using established acceptance and performance criteria.
- b. Calibrate and maintain equipment used for inspections and tests.

9. Criterion 9— Assessment/Management Assessment.

- a. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

10. Criterion 10— Assessment/Independent Assessment.

- a. Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.
- b. Establish sufficient authority and freedom from line management for independent assessment teams.
- c. Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.

SUSPECT/COUNTERFEIT ITEMS PREVENTION

This attachment provides information and/or requirements associated with DOE O 414.1D and is applicable to contracts in which the associated CRD (Attachment 1) is inserted.

1. **PURPOSE.** To set forth requirements for DOE and its contractor organizations, as part of their QAPs, to establish, document and implement effective controls and processes that will: (1) ensure items and services meet specified requirements; (2) prevent entry of Suspect/Counterfeit Items (S/CIs) into the DOE supply chain; and (3) ensure detection, control, reporting, and disposition of S/CIs.
2. **REQUIREMENTS.** The organization's QAP must:
 - a. Include a S/CI oversight and prevention process commensurate with the facility/activity hazards and mission impact.
 - b. Identify the position responsible for S/CI activities and for serving as a point of contact with the Office of Health, Safety, and Security.
 - c. Provide for training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs).
 - d. Prevent introduction of S/CIs into DOE work by—
 - (1) engineering involvement:
 - (a) in the development of procurement specifications;
 - (b) during inspection and testing; and
 - (c) when maintaining, replacing, or modifying equipment;
 - (2) identifying and placing technical and QA requirements in procurement specifications;
 - (3) accepting only those items that comply with procurement specifications, consensus standards, and commonly accepted industry practices; and
 - (4) inspecting inventory and storage areas to identify, control, and disposition for S/CIs.
 - e. Include processes for inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards. Also address the use of supporting engineering